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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/751,072	Applicant(s) EYCKERMAN ET AL.
	Examiner ZACHARY C. HOWARD	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 June 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,11,13 and 16 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,11,13 and 16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 22 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 6/9/09.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 6/9/09 has been entered in full. Claim 1 is amended. Claim 31 is canceled. Claims 2, 4-10, 12, 14, 15 and 17-30 were previously cancelled.

Claims 1, 3, 11, 13 and 16 are pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement of 6/9/09 has been considered.

Withdrawn Objections and/or Rejections

All objections and rejections of claim 31 set forth in the 3/9/09 Office Action are moot in view of Applicants' cancellation of this claim.

The objection to claim 1 at pg 5 of the 3/9/09 Office Action is *withdrawn* in view of Applicants' amendment to the claim.

Maintained Rejections

Claim Rejections – 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eyckerman et al (1999).

Eur Cytokine Netw. 10(4): 549-546; cited previously). This rejection was set forth previously and maintained at pg 2-5 of the 3/9/09 Office Action.

The 3/9/09 Office Action at pg 3 incorrectly stated that Eyckerman et al was cited on the 11/22/02 IDS. Instead, Eyckerman et al was originally cited on the PTO-892 accompanying the 4/22/08 Office Action.

Applicants' arguments (6/9/09; pg 4-8) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants reiterate arguments as to why Eyckerman et al (1999) do not teach each and every element of the claims; specifically, they do not teach a bait polypeptide because the myc-tag taught therein is not equivalent to a bait polypeptide (pg 5). Applicants argue that "the terms "bait" and "tag" are clearly different for the person ordinarily skilled in the art as used in the application. A "tag" is a short peptide that can be used for the identification or isolation of a protein. A "bait" is a polypeptide that is used to fish a prey out of a mixture of candidate interacting molecules" (pg 5-6). In support, Applicants point to Van Criekinge (1999; cited previously) and Hertveld et al (2003; newly cited).

Applicants' arguments have been fully considered but are not found persuasive. As set forth previously, while Van Criekinge teaches that fusion polypeptides comprising a bait polypeptide can also include an HA epitope tag (fused in-frame between the GAL4 DNA-binding domain and the bait polypeptide), Van Criekinge also teaches fusion polypeptides comprising a bait polypeptide without an HA epitope tag (pg 9). Furthermore, Van Criekinge describes a "bait" polypeptide only as "a protein of interest" (pg 4); this description does not exclude an epitope tag from being used as such "bait" proteins. Furthermore, while Applicants argue a size distinction between an epitope tag (e.g., myc) and a bait polypeptide, Van Criekinge does not teach such a distinction, or any size limitation for the bait polypeptide. "Short" peptides have been used in the relevant art as bait in a yeast two-hybrid screen. For example, Clayberger et al (U.S. Patent 5,935,797; published 8/10/99) teaches use of a 15 amino acid bait in a two-hybrid screen: "pXL-17 was created as the bait plasmid in the yeast two hybrid screen ... In pXL-17, the peptide DQ65-79 was fused to the carboxyl terminal end of the yeast

GAL4 DNA binding domain (GAL4-BD)" (col 9, lines 22-26). The myc tag itself has been used as such bait; for example, Fujiwara et al (2002. Biochemistry. 41(42): 12729-38) teaches a bait-prey system wherein the bait comprised a single or five copies of the myc epitope tag (pg 12733). Furthermore, the relevant art has also used fragments of the myc protein comprising the myc epitope tag as bait in two-hybrid screening. The myc epitope tag is located in the C-terminal region of the protein between amino acids 408-439 (pg 2 of Hilpert et al, 2001. Protein Engineering. 14(10): 803-806; 11 pages as printed). Estojak et al (1995. Molecular and Cellular Biology. 15(10): 5820-5829) teaches a bait molecule wherein "pLexA-Myc expresses the carboxy terminal 176 amino acids of human c-Myc" (pg 5821). Bao et al (1996. Oncogene. 12: 2171-2176) teaches an interaction trap wherein "[t]he Lex-C-myc bait contains the carboxy-terminal 176 amino acids of human C-myc" (pg 2175). Bannasch et al (1999. Oncogene. 18: 6810-6817) teach a bait construct encoding a fusion protein of Gal4 DNA binding domain (Gal4 BD) and "the central and C-terminal portion of the Myc protein (aa 180-436) (MYC-CT)" (pg 6811). Junqueira et al (2003. Oncogene. 22: 2772-2781) teach "Myc282-437 bait lacking the last three amino acids" (pg 2773). Finally, the two-hybrid assay taught by Van Criekinge is not the only prior art which informs the "bait" terminology used in the instant claims. The instantly claimed "receptor-interaction trap" is significantly different in structure from the two-hybrid assay described by Van Criekinge. In the instant "trap" the bait is fused to a membrane-spanning receptor rather than to a DNA-binding portion of transcription factor as in the "standard" two-hybrid assay taught by Van Criekinge. Other variants of the two-hybrid assay are taught by the prior art; for example, Zhang et al (2000. Nature Biotechnology. 18: 71-74) teaches that "[t]he repressor reconstitution assay we used to isolate peptide-binding peptides is one of many variants of the two-hybrid concept" (page 73). Zhang does not use the term "bait", however, the skilled artisan would recognize that the "target peptide" used in Figure 1 is analogous to the "bait" polypeptide (the "library encoded peptide" being analogous to a "prey" peptide). Zhang teaches that the target peptide is "an epitope of 13-14 amino acids" and is fused to a DNA-binding domain. Therefore, the prior art appreciates that bait polypeptides can be short peptides including epitopes.

Furthermore, the specification is silent as to any size constraint on the bait polypeptide, and defines a "heterologous bait polypeptide" only as "a polypeptide comprised in the cytoplasmic domain of a receptor, and indicates that the polypeptide is within the cytoplasmic domain, or fused to the cytoplasmic domain; there is another polypeptide that is not present in the cytoplasmic domain of the non-recombinant receptor" and that the term "[b]ait" as used herein means that this polypeptide can interact with other polypeptides not belonging to the normal receptor complex" (¶ 64, pg 15). This definition provides no limitation on the size of the "heterologous bait polypeptide". Nothing in this definition excludes peptides or other small polypeptides. Thus, nothing in this definition excludes the heterologous myc tag found in the receptor taught by Eyckerman.

With respect to Hertveld et al (2003; newly cited), Applicants argue that "the authors mention "tagged baits" ... indicating the different functions - and meaning - of the terms tag and bait. Especially in the field of TapTag technology, where protein complexes are immunoprecipitated, there is extensive evidence for the different meaning of both terms. It is important to stress that tags are chosen in such a way that they do not interfere with the bait action and will not act as a bait, as otherwise the combination of bait and tag would give raise to false positives" (pg 6).

Applicants' arguments have been fully considered but are not found persuasive. Applicants do not point to any particular teachings in Hertveld et al that teach that the terms "tag" and "bait" are mutually exclusive; i.e. that a tag cannot be used as a bait. Hertveld et al does not use the term "tagged baits" as referred to by Applicants. The Abstract of Hertveld et al contains a single reference to "[b]aits tagged with an N-terminal E-tag and a C-terminal His₆-tag"; which simply shows that a particular bait (Gal80) used by Hertveld et al can be used with two particular tags (E-tag and His₆-tag). This teaching provides no evidence that the terms "tag" and "bait" are mutually exclusive; i.e., that a tag cannot also be used as a bait. Furthermore, Hertveld et al do not refer to "TapTag" technology; therefore, Applicants have provided no evidence supporting the arguments that "in the field of TapTag technology, where protein complexes are immunoprecipitated, there is extensive evidence for the different

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meaning of both terms. It is important to stress that tags are chosen in such a way that they do not interfere with the bait action and will not act as a bait, as otherwise the combination of bait and tag would give raise to false positives". As stated in MPEP 2145, "arguments of counsel cannot take the place of factually supported objective evidence".

At page 6-7, Applicants provide new arguments in response to the Examiner's response set forth in the previous Office Action (3/9/09). Specifically, Applicants argue that the reference of Fujiwara et al (cited previously and herein) provides results that would lead a person of ordinary skill in the art to "conclude that the myc tag is indeed NOT suitable as bait (e.g., that a prey polypeptide which binds to myc and contains an activation site inhibitor would NOT be capable of inhibiting the claimed receptors)". Applicants argue that the results observed for a single myc tag and the monoclonal antibody 9E10 are negative (citing page 12733 of Fujiwara). Applicants argue that "[o]nly in the case of antibody 3DX, obtained after four rounds of mutagenesis, could some activity could [sic] be detected with a single myc tag. However, this activity is far below the level of the positive control and in the range of the background signal (Figure 3B of Fujiwara et al.)" (pg 6-7). Applicants argue that these results show that "the receptor taught by Eyckerman cannot fulfill the functional limitation of being activated by binding of a ligand and a prey polypeptide" (pg 7).

Applicants' arguments have been fully considered but are not found persuasive. Fujiwara et al do not state that the activity resulting from 3DX interacting with the myc tag is "in the range of the background signal". This appears to be an interpretation by Applicants of the results shown in Figure 3B. Instead, Fujiwara et al state that "[u]nder the same conditions using a single Myc tag as a bait, growth of yeast transformed with the 9E10 ScFv prey plasmid could hardly be detected, while cells transformed with a 3DX prey plasmid showed significant growth" and "[t]hese results were then extended using a quantitative β -galactosidase assay (Figure 3B)" (pg 12733). Figure 3B clearly shows that the level of β -galactosidase in the sample termed "3DX 1 Myc" is quantitatively higher than the background level observed in the sample termed "vector 1 Myc". Thus, Fujiwara et al provide two assays (growth and β -galactosidase)

demonstrating that the interaction between a single myc tag (as bait) and a 3DX ScFv (as prey) is detectable. Thus, Applicants' argument that the skilled artisan would "conclude that the myc tag is indeed NOT suitable as bait" based on the teachings of Fujiwara et al is not found persuasive. Furthermore, the bait-prey system used by Fujiwara et al is has significant structural differences from the receptor used by Eyckerman et al and does not provide evidence that the myc tag in the receptor taught by Eyckerman could not function as a bait polypeptide.

At page 7, Applicants provide further new arguments in response to the Examiner's response set forth in the previous Office Action (3/9/09). Specifically, Applicants argue that "the myc tag as used and understood by the person of ordinary skill in the art is a peptide of 11 AA (sequence EEQKLISEEDL – as present in pGBKT7 cited by Fujiwara et al. - or EEQKLISDEEL). The fact that these are the myc tags found in practical use is recognized in Hilpert et al, 2001, cited by the examiner (p2 as printed). The publication of Estojak et al (1995), Bao et al. (1996), Bannasch et al. (1999) and Junqueira et al. (2003) use far larger fragments (at least 176 AA) as baits, and therefore, those baits are not covered by the definition of the myc tag, as used by the person skilled in the art. Accordingly, one of ordinary skill in the art would conclude that the myc tag alone is not the bait used in Estojak et al (1995), Bao et al. (1996), Bannasch et al (1999) and Junqueira et al (2003)" (pg 7).

Applicants' arguments have been fully considered but are not found persuasive. The Examiner did not take the position that "the myc tag alone" is the bait used in Estojak et al (1995), Bao et al. (1996), Bannasch et al (1999) and Junqueira et al (2003). Instead, these references were cited in support of the argument that the "myc tag" as taught by Eyckerman et al is encompassed by the term "bait" used in the instant claims. These specific references were cited to show that the relevant art "has also used fragments of the myc protein comprising the myc epitope tag as bait in two-hybrid screening". These references simply provide evidence that the presence of a myc epitope tag does not exclude a polypeptide fragment from being a bait polypeptide. Different art was cited providing evidence that "short" peptides have been used as bait in a two hybrid screen; specifically, Clayberger et al (U.S. Patent 5,935,797), Fujiwara et

al (2002) and Zhang et al (2000). Applicants' response does not address the references of Clayberger et al or Zhang et al. Furthermore, Fujiwara et al provides evidence of use of a myc tag itself as a bait polypeptide. Thus, it is maintained that the relevant art appreciates that bait polypeptides can be short peptides including epitopes, and that the "myc tag" as taught by Eyckerman et al is encompassed by the term "bait" used in the instant claims.

At pg 7-8 of the 6/9/09 response, Applicants reiterate arguments from pages 6-7 of the 7/24/08 response. Specifically, the third paragraph beginning on page 7 of the 6/9/09 response is identical to the second paragraph on page 6 of the 7/24/08 Office Action, and the first paragraph beginning on page seven of the 6/9/09 response is identical to the third paragraph beginning on page 6 and continuing to page 7 of the 7/24/08 Office Action. These arguments were previously considered and addressed at pg 7-10 of the 11/10/08 Office Action. For clarity, this response is reiterated herein.

Applicants further argue (pg 7) that the prey coupled to an inhibitor expressed in the claims is an essential element of the invention and Eyckerman does not disclose a prey polypeptide. Applicants argue that the skilled artisan "would have no knowledge (or motivation) that such a prey fusion construct could be used to inhibit the receptor" (pg 7). Applicants further argue that "even using the disclosure of the present application, it is unlikely that the Eyckerman receptor could be inhibited without burdensome experimentation in creating the anti-myc inhibitor fusion necessary" for such inhibition, and thus no reasonable expectation of success exists in modifying the teachings of Eyckerman to arrive at the present claims (pg 7).

Applicants' arguments have been fully considered but are not found persuasive. The instant claims do not require that the complete structure of the prey polypeptide of the inhibitory fusion protein is known prior to constructing a receptor that can be inhibited by said fusion protein. The instant specification discloses prior art methods for identifying bait-prey interactions (¶ 4-7 of the published application). Furthermore, Example 2 of the instant application references European patent application 00201771.3, which describes methods of screening libraries for prey molecules that interact with specific bait polypeptides. Thus, to meet the functional limitation of the

claims, the recombinant receptor taught by Eyckerman only needs to be functionally capable of activation when contacted by any prey molecule that could be identified by the disclosed methods of screening with the bait polypeptide. Eyckerman itself does not teach whether or not the recombinant receptor taught therein would be inhibited by a fusion polypeptide comprising a prey molecule and at least one of an inhibitor of the activation selected from the group consisting of a member of the SOCS family, JAK-phosphatase and STAT-phosphatase. To meet this functional limitation, the recombinant receptor taught by Eyckerman only needs to be functionally capable of being inhibited when contacted by a fusion protein as recited in the claims. As far as the Examiner can determine, the specific mutant receptor described by Eyckerman would be inhibited if contacted with a fusion polypeptide such as those described in the instant application (e.g., one comprising both a prey polypeptide that binds to myc and another one that comprises an inhibitor of activation). With these conditions, where the product seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Applicants have not provided any evidence that the recombinant receptor taught by Eyckerman would not be inhibited if used with a fusion polypeptide as recited in the instant claims. As stated in MPEP 2145, "arguments of counsel cannot take the place of factually supported objective evidence".

As set forth previously, the rejected claims are directed to a genus of recombinant receptors, wherein the scope of the genus is partly defined by a functional interaction with a genus of fusion proteins comprising prey polypeptides and inhibitors of activation. The rejected claims are not directed to a fusion protein comprising a prey polypeptide *per se*, either alone or in combination with receptor. As such, the rejection of the claims under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eyckerman et al, 1999 does not require that Eyckerman actually teach a fusion protein capable of inhibiting the receptor. If the receptor described by Eyckerman is inherently capable of being inhibited when contacted with a prey polypeptide recited in the claims, then it meets the recited functional limitations.

Applicants further argue (pg 8) that "[t]he myc-tag is a short peptide of 10 amino acids that can be bound by an antibody, but is generally incapable of binding to a normal protein by the classical protein-protein interaction normally associated with cellular function: although the tag is extensively used in the art, there are no protein-protein interactions described with the myc-tag other than myc-binding antibodies. Thus, inhibition of the myc-tagged protein of Eyckerman would only work through the cytoplasmic expression of a functional myc-binding antibody, fused to an inhibitor. It would have been clear to one of ordinary skill in the art that this would not work with classical heavy/light chain antibody complexes, as these are not found in the cytoplasm. If one of skill in the art attempted to develop a single chain antibody fused to an activation [sic, assumed "inhibitor"] domain, such development would not yield predictable results, as the exact folding and requisite S-S bridge formation would be unpredictable for such a molecule without extensive experimentation. Moreover, even if one could obtain such a construct, it is unsure whether the activation domain, fused to such a single chain antibody, could inhibit the recombinant receptor in coordination while the anti-myc portion is bound to the myc-tag. Compared with the bait/prey interactions, the anti-myc antibody interaction would be a bulky complex where steric hindrance would be expected to prevent inhibition of the receptor. Thus, applicants respectfully submit that the receptors of Eyckerman cannot be inherently capable of being inhibited when contacted with an anti-myc/inhibitor fusion as the requisite anti-myc polypeptides have not been developed for intracellular use and there is no reasonable expectation of the successful function even if developed" (pg 8).

Applicants' arguments have been fully considered but are not found persuasive. Applicants provide no evidence supporting the assertion that the myc tag cannot be bound by any prey polypeptide other than an anti-myc antibody. As stated in MPEP 2145, "arguments of counsel cannot take the place of factually supported objective evidence". The Examiner does not dispute that it might be difficult to construct an antibody, even a single-chain antibody fusion, which functions as a prey molecule in the claims of the instant invention. However, the rejection of claim 1 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over

Eyckerman et al, 1999 does not require that the skilled artisan use an anti-myc antibody as part of the prey molecule. As noted above, the instant specification discloses prior art methods for identifying bait-prey interactions (¶ 4-7 of the published application). Furthermore, Example 2 of the instant application references European patent application 00201771.3, which describes methods of screening libraries for prey molecules that interact with specific bait polypeptides. Thus, there is no need to use an anti-myc antibody in the prey molecule. If the recombinant receptor taught by Eyckerman can be functionally activated by any single prey molecule (such as that identified from a library of prey molecules), then it meets the functional limitation of the claims. Eyckerman is silent as to whether the receptor has this functionality, thus the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

In summary, it is maintained that the "myc tag" as taught by Eyckerman et al is encompassed by the term "bait" used in the instant claims. Therefore, the rejection is maintained herein for the reasons set forth previously.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647